



Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Virginia Department of Health (VDH)
Virginia Administrative Code (VAC) citation	12 VAC 5-165-10 et seq.
Regulation title	Regulations for the Repacking of Crab Meat for Human Consumption
Action title	Modify repacking of crab meat requirements.
Date this document prepared	12/06/2010

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The Regulations for the Repacking of Crab Meat for Human Consumption (12 VAC 5-165-10 et seq.) pertain to the practice of transferring crab meat from the container of one establishment, as the term is defined in § 28.2-800 in the *Code of Virginia*, into the container of an establishment certified by the Division of Shellfish Sanitation to repack crab meat. When these regulations were adopted in 2000, they were developed to address a situation where one Virginia-certified crab meat dealer would purchase crab meat packed by another certified crab meat dealer, whether of a domestic or foreign origin, and repack the meat into a container. Most crab meat shipped into the United States now originates from a multitude of different processing facilities but is shipped in one cargo container by one exporter to the U.S. The one-on-one relationship between the original processing plant and the Virginia-certified dealer no longer exists in most instances. Several of the requirements that depended upon this relationship cannot be reliably met. The State Board of Health (the "board") seeks to revise the regulations to reflect this change in order to assure the safety of crab meat repacked in Virginia.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Section 28.2-800 et seq. of the Code provides the statutory authority for promulgating regulations governing finfish, shellfish and crustacea so as to protect public health and the environment. Specifically, § 28.2-801.B provides that the board may promulgate regulations that are necessary to implement the health and sanitation statutory provisions that relate to finfish, shellfish and crustacea.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

Some of the provisions of 12 VAC 5-165-10 et seq. cannot be met by Virginia-certified repacking establishments because of changes in the way that crab meat is being initially packed in foreign countries and shipped into the U.S. Due to this change, the board must develop alternative requirements that Virginia establishments, where crustacea, finfish or shellfish are transported, held, stored, processed, packed, repacked or pasteurized in preparation for marketing, can reasonably meet and that will adequately address the risks of food borne disease that improperly repacked crab meat pose to the environment and to the public at large.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

The board will propose eliminating 12 VAC 5-165-90, which is a requirement for a repacker to obtain a record of shipping temperatures for imported crab meat. Such a temperature record is almost impossible to obtain given the magnitude of the current food shipping system. The board will propose that establishments use microbiological sampling results and organoleptic sensing to check for temperature abuse of the crab meat.

The board proposes modifying 12 VAC 5-165-100.A, which addresses sampling requirements for imported crab meat to be repacked. When a repacker is importing crab meat from one source plant, then the original requirement for the first two shipments to be sampled, followed by a minimum of quarterly sampling, would remain as originally established. However, when a repacker uses crab meat shipped by one exporter, but which has been picked by more than one originating plant in the foreign country, then lot-by-lot sampling would be required.

The board proposes modifying 12 VAC 5-165-100.B, which addresses organoleptic sensing. There is a lack of local capacity to train persons in organoleptic sensing to the level of being certified in seafood decomposition, which has made this regulation impractical. In its place, repacking establishments would organoleptically sense, to the best of the individual's capability, each container when opened and keep records attesting to this practice. Unsatisfactory containers would be discarded and a record kept of this process.

The board proposes modifying 12 VAC 5-165-110, which addresses the verification of pasteurization of imported crab meat. Since crab meat is now being initially picked and packed by numerous facilities in

foreign countries prior to being shipped by one exporter, obtaining letters from each facility, which state that the meat has been pasteurized, is at best an unreliable verification tool. Instead of requiring such letters, the board will place the burden of assuring this process upon the repacker. Results of microbiological analyses on a lot-by-lot basis will help assure that a satisfactory heat treatment has been used.

The board will evaluate 12 VAC 5-165-160, which forbids the blending of crab meat from more than one foreign processor. It is nearly impossible for regulants to comply with this regulation since most of the imported crab meat has been compiled from many establishments before being exported from the foreign country. The original purpose of this regulation was to aid in trace-back efforts in the event of an illness. If the board deletes this regulation and there is an outbreak of food-borne illness associated with a particular exporter, then such a deletion may result in a wider ban on repacking those imports.

The board may address other sections of this regulation during this process.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

The only viable option is to leave the regulations as they are currently written. However, in light of the changes in the way that crab meat is being initially packed in foreign countries and shipped into the U.S., amending the regulations will better enable the board to effectively carry out its public health responsibilities under title 28.2 of the Code.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

VDH is seeking comments on the intended regulatory action, including but not limited to: 1) ideas to assist in the development of a proposal; 2) the costs and benefits of the alternatives stated in this background document or other alternatives; and, 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code. Information may include 1) projected reporting, recordkeeping and other administrative costs; 2) probable effect of the regulation on affected small businesses; and, 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Town Hall web site (<http://www.townhall.virginia.gov>) or by mail, email or fax to Bob Croonenberghs, 109 Governor Street, Suite 614, Richmond, Virginia 23219, (804)864-7477 (phone), (804)864-7481 (fax), bob.croonenberghs@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

In addition, the agency is seeking information on (1) the continued need for the regulation; (2) the complexity of the regulation; (3) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and, (4) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

The agency will hold a public hearing; notice of the hearing will be posted on the Virginia Regulatory Town Hall website (www.townhall.virginia.gov) and can be found in the Calendar of Events section of the Virginia Register of Regulations. Both oral and written comments may be submitted at that time.

Participatory approach

Please indicate, to the extent known, if advisers (e.g., ad hoc advisory committees, technical advisory committees) will be involved in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

VDH is using the participatory approach in the development of the proposal. The agency will hold meetings with industry and will request comments from the Virginia Seafood Council and Marine Products Board. All interested parties who would like to participate should contact Bob Croonenberghs, 109 Governor Street, Suite 614, Richmond, Virginia 23219, (804)864-7477 (phone), (804)864-7481 (fax), bob.croonenberghs@vdh.virginia.gov.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

- 1) The proposed modification of these regulations will neither strengthen nor erode the authority and rights of parents in the education, nurturing, and supervision of their children.
- 2) The proposed modification of these regulations will neither encourage nor discourage economic self-sufficiency, self-pride, nor the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents.
- 3) The proposed modification of these regulations will neither strengthen nor erode the marital commitment.
- 4) The proposed modification of these regulations will neither increase nor decrease disposable family income.

Periodic review - Public comment

If this NOIRA is not the result of a periodic review of the regulation, please delete this entire section.

If this NOIRA is the result of a periodic review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 36, e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.

Commenter	Comment	Agency response
No one	none	none

The regulations, 12 VAC-165 *et seq.*, are necessary for the protection of public health, safety and welfare and are clearly written. However, since crab meat is now processed differently in foreign countries before being shipped into the U.S., the board needs to make adjustments in the regulations to address these changes. The regulations are based on the best reasonably available and reliable, scientific, economic, and other information concerning the need for, and consequences of, the regulations. The regulations are designed to achieve their intended objective in the most efficient, cost-effective manner. In addition, the regulations are in accordance with statutory provisions related to impact on small businesses. Further, the regulations do not adversely impact existing and potential Virginia employers and their ability to maintain and increase the number of jobs in the Commonwealth.

Small business impact review

*Pursuant to § 2.2-4007.1 E and F each existing regulation shall be reviewed **at least once every five years** to ensure that it minimizes the economic impact on small businesses.*

If this NOIRA will not include a review of the entire regulation for small business impact, please delete this entire section.

If this NOIRA will include a review of the entire regulation for small business impact, please include, pursuant to § 2.2-4007.1 E and F, a discussion of the agency’s consideration of: (1) the continued need for the regulation; (2) the complexity of the regulation; (3) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (4) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, include a discussion of the agency’s determination whether the regulation should be amended or repealed, consistent with the stated objectives of applicable law, to minimize the economic impact of regulations on small businesses.

- (1) It is necessary to maintain most of these rules because the picking, packing and repacking of crab meat involves intensive hand contact, which provides the means for pathogenic organisms to be deposited on the cooked meat, and the meat is a ready-to-eat food.
- (2) These regulations are not particularly complex; they are detailed and specific to make them clear in their application.
- (3) These regulations do not overlap, duplicate or conflict with federal or state law or regulation.
- (4) These regulations were last evaluated in 2003-2004.

VDH’s Division of Shellfish Sanitation has evaluated the regulations and has determined that they do not impose any unnecessary economic burdens on small businesses. Furthermore, the board will review the proposed amendments to ensure that they do not impose any unnecessary economic burdens on small businesses.